

Application No.: 10/691,849
Amendment and Response dated February 26, 2008
Reply to Office Action of November 28, 2007
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Remarks/Arguments:

Introduction

Claims 31-65 are pending. Claims 1-30 have been canceled. Claims 34, 39, 47 and 55 are withdrawn. Claims 31, 45 and 56 have been amended to include an endovascular graft comprising a generally tubular body having a proximal end and a distal end, a proximal inflatable cuff disposed at or near the proximal end of the body, a distal inflatable cuff disposed at or near the distal end of the body and an inflatable channel in fluid communication with the proximal and distal cuffs. Support for these amendments may be found in the specification in paragraphs [0077], [0079] and [0086]. No new matter has been introduced with these claim amendments. Entry of the claim amendments is respectfully requested.

Section 112 Rejections

Claims 51, 52 and 63 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the examiner alleges that the “specification fails to provide antecedent basis and support for the embolic material consisting essentially of PEGDA of molecular weight between 700-800.” Applicants respectfully traverse.

Claims 51 and 63 set forth that “the polyethylene glycol diacrylate consists essentially of polyethylene glycol diacrylate having a molecular weight between 700 and 800”. In the specification at paragraph [0061] or at page 12, line20, it is described that “PEGDA having a molecular weight between about 700 and 800” may be used. Accordingly, it is respectfully submitted that claims 51, 52 and 63 are fully supported by the specification. Reconsideration and withdrawal of the Section 112 rejection of claim 51, 52 and 63 are respectfully requested.

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Section 102 Rejections

Claims 31-33, 35-38, 40-46, 48-54 and 56-65 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 7,714,661 to Chobotov et al. (hereinafter "Chobotov").

Chobotov fails to disclose, teach or suggest a delivery device for embolic material configured to access perigraft space between an endovascular graft and a body lumen wall. As Chobotov is silent on this aspect, the Examiner must then properly apply an inherency argument to the missing descriptive matter of Chobotov. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Crown Oper. Int'l Inc. v. Solutia Inc.*, 289 F.3d 1367, 62 U.S.P.Q.2d 1917 (Fed. Cir. 2002). Further, inherency may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient for a *prima facie* case of anticipation. *Scaltech Inc. v. Retec/Tetra L.L.C.*, 153 F.3d 1193, 51 U.S.P.Q.2d 1055 (Fed. Cir. 1999). Occasional results are not inherent. *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1365, 52 U.S.P.Q.2d 1303, 1306 (Fed. Cir. 1999).

Thus, claims 31-33, 35-38, 40-46, 48-54 and 56-65 are patentably distinct over Chobotov. Reconsideration and withdrawal of the rejections of claims 31-33, 35-38, 40-46, 48-54 and 56-65 are respectfully requested.

Section 103 Rejections

Claims 31-33, 35, 36, 40-46 and 50-54 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Application Publication No. 2001/0029349 to Leschinsky (hereinafter "Leschinsky") in view of U.S. Patent No. 6,958,212 to Hubbell et al. (hereinafter "Hubbell"). Applicants respectfully traverse.

Leschinsky discloses that a chemical solution of glutaraldehyde or carbodiimide which is used to strengthen an aneurismal wall by crosslinking with the collagen within the wall, as follows:

The purpose of the chemical solution is to strengthen aneurysmal wall 23 by actually changing the nature of the wall 23, i.e. crosslinking the collagen in the wall 23. ... [T]he preferred solutions are aldehydes and especially glutaraldehyde.... Another possible crosslinking agent is carbodiimide.... (Leschinsky, paragraphs [0042] - [0043]) (emphasis added)

Thus, Leschinsky teaches a specific solution, i.e., a solution of glutaraldehyde or carbodiimide, which is to be introduced into a bodily lumen to interact with the collagen within an aneurismal wall. Leschinsky, however, fails to teach or suggest that this chemical solution of glutaraldehyde or carbodiimide is in itself a curable embolic material. Indeed, Leschinsky specifically describes that its chemical solutions are to interact with a vessel wall, but are not curable by themselves, as they are to be removed from the bodily lumen, as follows:

[A] chemical solution, preferably glutaraldehyde, other examples of which were described and listed in reference to first and second embodiments, is pumped through tube 150, infusion/vacuum lumen 132 and port 152 into treatment chamber 41. As indicated above the chemical solution actually changes the nature of wall 22. Next, the chemical solution is pumped out of port 152, through infusion/vacuum lumen 132, and out tube 150. The flushing and chemical solution infusion cycles may be repeated as necessary. ... Following treatment with the chemical solution another flushing solution may be employed to remove excess chemical solution from treatment chamber 41. (Leschinsky, paragraph [0050], lines 10-26) (emphasis added)

Thus, Leschinsky specifically teaches this chemical solution which crosslinks with collagen, but is not by itself a curable solution.

At paragraph [0052], Leschinsky teaches that a filling material 170 may be solidified or dried between an aneurysm wall and a stent or stent/graft device. No details, including even if the filling material is a curable material, is provided by Leschinsky.

In contrast to Leschinsky's non-curable solution of solution of glutaraldehyde or carbodiimide for interacting with collagen in a vessel lumen, or a material that merely solidifies or dries, Hubbell is directed to curable biomaterials. (Hubbell, column 1, 67, to column 2, line 1). Hubbell, teaches that pentaerythritol tetra 3(mercaptopropionate) is to be combined with a particular polyethylene glycol diacrylate, i.e., a polyethylene glycol diacrylate having a molecular weight of 570. (Hubbell, column 65, lines 35-37). Even when a 20,000 molecular weight polyethylene glycol diacrylate is considered by Hubbell, Hubbell specifically teaches that its composition must necessarily still contain the 570 molecular weight polyethylene glycol diacrylate, as follows:

**Low molar content of a larger molecular weight precursor
(i.e., PEGDA 20,000 ...) can replace some of the PEGDA 570,
creating a bimodal system.** (Hubbell, column 68, lines 22-
24)(emphasis added)

Thus, Hubbell fails to teach or suggest an embolic material embolic material comprising polyethylene glycol diacrylate where the polyethylene glycol diacrylate comprises a molecular weight between 700 and 800, as set forth in independent claims 31 and 45. Moreover, Hubbell further fails to teach or suggest an embolic material embolic material comprising polyethylene glycol diacrylate where the polyethylene glycol diacrylate consists essentially of polyethylene glycol diacrylate having a molecular weight between 700 and 800, as set forth in dependent claims 41 and 51.

The only teaching of a an embolic material embolic material comprising polyethylene glycol diacrylate where the polyethylene glycol diacrylate comprises a molecular weight between 700 and 800 or an embolic material embolic material comprising polyethylene glycol diacrylate where the polyethylene glycol diacrylate consists essentially of polyethylene glycol

diacrylate having a molecular weight between 700 and 800 is the subject application. To be of any use in the office action, the Examiner must modify the teachings of Hubbell to exclude its necessary molecular weight polyethylene glycol diacrylate and then modify the molecular weight in an attempt to read on the claims of the present invention. It is well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness and any attempt at hindsight reconstruction using Applicants' disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

As the only teaching of embolic materials having polyethylene glycol diacrylate of the claimed molecular weight is the Applicants' specification and further as Hubbell teaches away from embolic materials not having polyethylene glycol diacrylate of a 570 molecular weight, it is respectfully submitted that Hubbell in combination with Leschinsky fails to teach or suggest the subject matter as presently defined in independent claims 31 and 45.

At paragraph [0061] of the subject specification, specific ranges, including PEGDA having a molecular weight of between about 700 and 800, are described. As described in paragraph [0065] of the subject specification, increased viscosity of the uncured material is desirable for managing endoleaks. It is respectfully submitted that selecting a PEGDA having a molecular weight of between about 700 and 800 is one means of achieving the desired viscosity result to the exclusion of the use of lower molecular weight PEGDA which will necessarily have lower viscosity characteristics.

Furthermore, Leschinsky and Hubbell fail to teach or suggest the use of an endovascular graft comprising a generally tubular body having a proximal end and a distal end, a proximal inflatable cuff disposed at or near the proximal end of the body, a distal inflatable cuff disposed at or near the distal end of the body and an inflatable channel in fluid communication with the proximal and distal cuffs. While Chobotov does teach an inflatable endovascular graft, Chobotov is silent on the use of curable embolic material within perigraft space between its endovascular graft and a body lumen wall. In establishing a *prima facie* case of obviousness,

the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* It would only be through hindsight reconstruction and very selective picking and choosing would an office action attempt to reach the present invention through the combination of Leschinsky, Hubbell and Chobotov. It is also well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993). Such hindsight reconstruction by the Examiner is clear as both Wilde and Ellis individually fail to teach or suggest a non-rectilinear pass-through (wavy) path in their respective cleaning.

Thus, it is respectfully submitted that claims 31-33, 35, 36, 40-46 and 50-54 are patentably distinct over Leschinsky and Hubbell, individually or in combination. Reconsideration and withdrawal of the rejection submitted that claims 31-33, 35, 36, 40-46 and 50-54 are respectfully requested.

Claims 37, 38, 48, 49 and 56-65 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leschinsky in view Hubbell and further in view of U.S. Patent No. 5,646,007 to Enomoto et al. (hereinafter "Enomoto"). Applicants respectfully traverse.

Enomoto merely teaches that HEPES or glycylglycine may be used as buffers to control the pH of a thrombin reagent and a chromogenic substrate reagent. (Enomoto, column 5, lines 40-44). It is respectfully submitted that the control of pH of solutions of thrombin and chromogenic substrate reagents would not provide motivation to one of ordinary skill in the art to modify the teachings of Leschinsky and/or Hubbell, individually or in combination, to arrive at, *inter alia*, the specifically defined curable embolic materials of the present invention, including, *inter alia*, the claimed buffers of independent claim 56, as Enomoto fails to teach or suggest that its buffers may be used with the claimed constituents and/or may be used *in vivo*.

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Furthermore, Enomoto fails to cure the deficiencies of Leschinsky and Hubbell. For example, Leschinsky, Hubbell and Enomoto, individually or in combination, fail to teach or suggest, *inter alia*, an embolic material comprising polyethylene glycol diacrylate where the polyethylene glycol diacrylate comprises a molecular weight between 700 and 800, as set forth in independent claim 56, and/or an embolic material comprising polyethylene glycol diacrylate where the polyethylene glycol diacrylate consists essentially of polyethylene glycol diacrylate having a molecular weight between 700 and 800, as set forth in dependent claim 63.

Thus, it is respectfully submitted that claims 37, 38, 48, 49 and 56-65 are patentably distinct over Leschinsky, Hubbell and Enomoto, individually or in combination. Reconsideration and withdrawal of the rejection submitted that claims 37, 38, 48, 49 and 56-65 are respectfully requested.

Summary

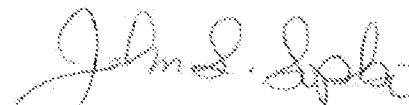
Therefore, Applicants respectfully submit that independent claims 31, 45 and 56, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

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Respectfully submitted,

A handwritten signature in cursive script, appearing to read "John S. Sopko", written over a horizontal line.

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